

## CLAIMS

1. A sustained release drug delivery device comprising:
- a) a drug core comprising a therapeutically effective amount of at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect;
  - b) a unitary cup essentially impermeable to the passage of said agent that surrounds and defines an internal compartment to accept said drug core, said unitary cup comprising an open top end with at least one recessed groove around at least some portion of said open top end of said unitary cup; and
  - c) a permeable plug which is permeable to the passage of said agent, said permeable plug is positioned at said open top end of said unitary cup wherein said groove interacts with said permeable plug holding it in position and closing said open top end, said permeable plug allowing passage of said agent out of said drug core, through said permeable plug, and out said open top end of said unitary cup.
2. The sustained release drug delivery device according to Claim 1, wherein said unitary cup is made of polymer or metal.
3. The sustained release drug delivery device according to Claim 1, wherein said unitary cup further comprises an integral suture tab.
4. The sustained release drug delivery device according to Claim 3, wherein said integral suture tab has a hole through the proximal end through which a suture can be placed to anchor the device to a structure.
5. The sustained release drug delivery device according to Claim 3, wherein said unitary cup is made of silicone.
6. The sustained release drug delivery device according to Claim 5, wherein said permeable plug is made of PVA.

7. The sustained release drug delivery device according to Claim 1, wherein said unitary cup further comprises a plurality of recessed grooves around at least some portion of said open top end of said unitary cup.

8. The sustained release drug delivery device according to Claim 1, wherein said agent is a low solubility agent.

9. The sustained release drug delivery device according to Claim 1, wherein said agent is selected from a group consisting of immune response modifiers, neuroprotectants, corticosteroids, angiostatic steroids, anti-parasitic agents, anti-glaucoma agents, anti-biotics, anti-sense compounds, anti-angiogenic compounds, differentiation modulators, anti-viral agents, anti-cancer agents, and nonsteroidal anti-inflammatory agents.

10. The sustained release drug delivery device according to Claim 1, wherein said drug core comprises a plurality of agents.

11. The sustained release drug delivery device according to Claim 1, further comprising an impermeable plug with at least one passageway positioned between said drug core and said permeable plug.

12. A sustained release drug delivery device comprising:

a) a drug core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect;

b) a unitary cup essentially impermeable to the passage of said agent that surrounds and defines an internal compartment to accept said drug core, said unitary cup comprising an open top end and at least one lip around at least a portion of said open top end of said unitary cup; and

c) a permeable plug permeable to the passage of said agent positioned at said open top end of said unitary cup wherein said lip interacts with said permeable plug holding it in position and closing said open top end, said permeable plug allowing passage of said agent out of said drug core, through said permeable plug, and out said open top end of said unitary cup.

13. The sustained release drug delivery device according to Claim 12, wherein said lip extends around the entirety of said open top end of said unitary cup.

14. The sustained release drug delivery device according to Claim 12, wherein said unitary cup comprises a plurality of lips at said open top end of said unitary cup.

15. The sustained release drug delivery device according to Claim 12, wherein said drug core comprises an effective amount of a low solubility agent.

16. The sustained release drug delivery device according to Claim 12, wherein said agent is selected from a group consisting of immune response modifiers, neuroprotectants, corticosteroids, angiostatic steroids, anti-parasitic agents, anti-glaucoma agents, anti-biotics, anti-sense compounds, anti-angiogenic compounds, differentiation modulators, anti-viral agents, anti-cancer agents, and nonsteroidal anti-inflammatory agents.

17. The sustained release drug delivery device according to Claim 12, wherein said unitary cup is made of polymer or metal.

18. The sustained release drug delivery device according to Claim 12, wherein said unitary cup further comprises an integral suture tab.

10023391.121701

19. The sustained release drug delivery device according to Claim 18, wherein said unitary cup is made of silicone.

20. The sustained release drug delivery device according to Claim 19, wherein said permeable plug is made of PVA.

21. The sustained release drug delivery device according to Claim 18, wherein said suture tab has a hole through the proximal end through which a suture can be placed to anchor the device to a structure.

22. The sustained release drug delivery device according to Claim 12, wherein said drug core comprises a plurality of agents.

23. The sustained release drug delivery device according to Claim 12, further comprising an impermeable plug with at least one passageway positioned between said drug core and said permeable plug.

24. A method for providing controlled and sustained administration of an agent effective in obtaining a desired local or systemic physiological or pharmacological effect comprising inserting in a desired location in the body of a mammalian organism a sustained release drug delivery device comprising;

a) a drug core comprising a therapeutically effective amount of at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect;

b) a unitary cup essentially impermeable to the passage of said agent that surrounds and defines an internal compartment to accept said drug core, said unitary cup comprising an open top end with at least one recessed groove around at least some portion of said open top end of said unitary cup; and

c) a permeable plug which is permeable to the passage of said agent positioned at said open top end of said unitary cup wherein said groove interacts with said permeable plug holding it in position and closing said open top end, said permeable

plug allowing passage of said agent out of said drug core, through said permeable plug, and out said open top end of said unitary cup.

25. The method according to Claim 24, wherein said inserting step comprises inserting said sustained release drug device in a location selected from a group consisting of the vitreous of the eye, under the retina, and onto the sclera.

26. The method according to Claim 24, wherein said drug core comprises a plurality of agents.

27. The method according to Claim 24, wherein said inserting step comprises injecting said sustained release drug delivery device at the desired location.

28. A method for providing controlled and sustained administration of an agent effective in obtaining a desired local or systemic physiological or pharmacological effect comprising inserting at a desired location in the body of a mammalian organism a sustained release drug delivery device comprising;

a) a drug core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect;

b) a unitary cup essentially impermeable to the passage of said agent that surrounds and defines an internal compartment to accept said drug core, said unitary cup comprising an open top end and at least one lip around at least a portion of said open top end of said unitary cup; and

c) a permeable plug permeable to the passage of said agent positioned at said open top end of said unitary cup wherein said lip interacts with said permeable plug holding it in position and closing said open top end, said permeable plug allowing passage of said agent out of said drug core, through said permeable plug, and out said open top end of said unitary cup.

29. The method according to Claim 28, wherein said inserting step comprises inserting said sustained release drug delivery device in a location selected from a group consisting of the vitreous of the eye, under the retina, and onto the sclera.

30. The method according to Claim 28, wherein said drug core contains a plurality of said agents.

31. The method according to Claim 28, wherein said inserting step comprises injecting said sustained release drug delivery device at the desired location.

32. A method of manufacturing a sustained release drug delivery device comprising:

- a) manufacturing a drug core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect;
- b) providing a unitary cup essentially impermeable to the passage of said agent that surrounds and defines an internal compartment to accept said drug core, said unitary cup comprising an open top end with at least one recessed groove around at least some portion of said open top end of said unitary cup;
- c) inserting said drug core into said unitary cup; and
- d) filling a material which is permeable to the passage of said agent into said open top end of said unitary cup, allowing said material to solidify thereby forming a permeable plug wherein said groove interacts with said permeable plug holding it in position and closing said open top end, said permeable plug allowing passage of said agent out of said drug core, through said permeable plug, and out said open top end of said unitary cup.

33. The method of manufacturing a sustained release drug delivery device according to Claim 32, wherein said drug core is manufactured as a solid dose form.

34. The method of manufacturing a sustained release drug delivery device according to Claim 32, wherein said drug core is manufactured as a solid dispersion.

35. The method of manufacturing a sustained release drug delivery device according to Claim 32, comprising the further step of curing the assembled sustained release drug delivery device.

36. A method of manufacturing a sustained release drug delivery device comprising:

- a) manufacturing a drug core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect;
- b) providing a unitary cup essentially impermeable to the passage of said agent that surrounds and defines an internal compartment to accept said drug core, said unitary cup comprising an open top end with at least one lip extending around at least a portion of the said open top end of said unitary cup;
- c) inserting said drug core into said unitary cup; and
- d) filling a material which is permeable to the passage of said agent into said open top end of said unitary cup, allowing said material to solidify thereby forming a permeable plug wherein said lip interacts with said permeable plug holding it in position and closing said open top end, said permeable plug allowing passage of said agent out of said drug core, through said permeable plug, and out said open top end of said unitary cup.

37. The method of manufacturing a sustained release drug delivery device according to Claim 36, wherein said drug core is manufactured as a solid dose form.

38. The method of manufacturing a sustained release drug delivery device according to Claim 36, wherein said drug core is manufactured as a solid dispersion.

39. The method of manufacturing a sustained release drug delivery device according to Claim 36, comprising the further step of curing the assembled sustained release drug delivery device.

10023391.121701